

USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - public distribution

Date: 7/30/2004

GAIN Report Number: KS4039

Korea, Republic of

Food and Agricultural Import Regulations and Standards

Country Report

2004

Approved by:

Marcus E. Lower U.S. Embassy

Prepared by:

Seung Ah Chung

Report Highlights:

Updated on July 30, 2004

Section Updated: Section I, II, IV, V, VI, VII, IX, and APPENDIX

Updates include information on food labeling standards including imported organic products (Section II.A), meat imports (Section VI), mandatory assessments of biotech crops (Section VII), etc.

Includes PSD Changes: No Includes Trade Matrix: No Annual Report Seoul [KS1] [KS]

FOOD AND AGRICULTURAL IMPORTS REGULATIONS AND STANDARDS REPORT (FAIRS)

REPUBLIC OF KOREA

Last Updated: July 2004

Section(s) Last Updated: SECTIONS I, II, IV, V, VI, VII, IX, and APPENDIX

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Seoul, Korea for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about theses policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

TABLE OF CONTENTS		PAGE
1.	FOOD LAWS	3
II.	LABELING REQUIREMENTS	12
III.	PACKAGING & CONTAINER REQUIREMENTS	22
IV.	FOOD ADDITIVE REGULATIONS	23
٧.	PESTICIDE & OTHER CONTAMINANTS	24
VI.	OTHER REGULATIONS AND REQUIREMENTS	25
VII.	OTHER SPECIFIC STANDARDS	27
VIII.	COPYRIGHT/TRADEMARK LAW	29
IX.	IMPORT PROCEDURE	30
IX.	APPENDIX	31

APPENDIX I - PRIMARY KOREAN FOOD AGENCIES
APPENDIX II - WORLD TRADE ORGANIZATION (WTO) ENQUIRY POINT
APPENDIX III - LIST OF AVAILABLE REGULATIONS
APPENDIX IV - U.S. LABORATORIES AUTHORIZED BY KOREA
GOVERNMENT (KFDA)

SECTION I. FOOD LAWS AND IMPLEMENTING MINISTRIES

Following are the responsibilities of ministries and agencies involved with the Korean food system along with a brief description of relevant food laws.

A. Ministry of Health & Welfare:

The Ministry of Health & Welfare (MHW) relinquished most of its food regulation authorities to the Korea Food & Drug Administration (KFDA) in 1998. It did retain authority to legislate changes to the Food Sanitation Act and the Functional Food Act and their implementing Presidential Decree and Ministerial Ordinance. As MHW continues its reorganization, its direct linkage to food regulation fades. Today only one division within MHW oversees food policy and industry, whereas in 1998 a bureau handled these responsibilities.

1. Food Sanitation Act

The Food Sanitation Act is legislated by the National Assembly and is the legal basis for the food safety-related work conducted by MHW and KFDA. The Act aims to contribute to the improvement of national health by improving the quality of food nutrition and by preventing sanitary hazards and harm caused by food products.

2. Presidential Decree to the Food Sanitation Act

The Presidential Decree establishes provisions to implement the Food Sanitation Act. The decree provides more defined guidance on interpretation and implementation of the Food Sanitation Act.

3. Ministerial Ordinance to the Food Sanitation Act

The Ministerial Ordinance to the Food Sanitation Act prescribes more detailed guidance on how the Food Sanitation Act and Presidential Decree are to be implemented. This ordinance provides the nuts and bolts for conducting food related business in Korea, including the relevant penalties for compliance failure. The Ordinance also includes samples of the various types of forms needed in conducting food related business, including food imports. Other more detailed standards and regulations guiding food related business in Korea are provided in the form of the Food Code, Food Additive Code, Guidelines, Notices, etc. These detailed standards and regulations are the responsibility of KFDA.

4. Functional Food Act

The Functional Food Act, legislated by the Korean National Assembly, is the legal basis for MHW and KFDA oversight of functional foods (health foods & nutritional supplements). The Act aims to contribute to the improvement of national health and consumer protection by improving the safety and quality of functional foods and encouraging sound distribution and sales of such products.

5. Presidential Decree to the Functional Food Act

The Presidential Decree, issued December 18, 2003, established provisions to implement matters regulated by the Functional Food Act.

6. Ministerial Ordinance to the Functional Food Act

The Ministerial Ordinance, issued January 31, 2004, prescribed more detailed guidance on how the Functional Food Act and its Presidential Decree are to be implemented. This ordinance includes inspection of imported functional food, penalties for violations, applications for import inspection, advertisement, etc. Other more detailed standards and regulations guiding functional food related business in Korea are provided in the form of the Functional Food Code, Guidelines for Labeling of Functional Food, Guidelines for Advertisement of Functional Food, relevant Notices, etc. These detailed standards and regulations are the responsibility of KFDA.

B. Korea Food & Drug Administration:

KFDA is the principle government agency charged with ensuring that foods are safe, sound, wholesome and correctly labeled. KFDA is also responsible for ensuring that medicines are safe, effective, and that side effects are properly noted. Except for meat, poultry and dairy products (which are regulated by the Ministry of Agriculture & Forestry per the Livestock Product Processing Control Act), KFDA is responsible for setting and implementing standards and specifications for food in general, functional food, food additives, food packaging, containers and equipment. KFDA standards and specifications apply both to domestically produced and imported food products. Specific to imported food products, KFDA inspects products under provisions provided in the "Inspection Guidelines for Imported Food, etc." KFDA provides the English translation of this guideline on its website, although that information may not be the most updated version. The English translation is available on the KFDA's English website at http://www.kfda.go.kr/eng/download/eng2000-20.doc.

KFDA also sets and implements regulations governing safety assessment of agricultural products enhanced through biotechnology (GMO) and GMO labeling requirements for processed food products manufactured using GMO ingredients. Per the KFDA Guidelines for Recombinant Food Labeling, established in August 2000, starting July 13, 2001, KFDA implemented labeling requirements for processed food products containing GMO soybeans and corn, or their derivatives, as one or more of the top five major ingredients. Moreover, KFDA establishes the Korean Hazard Analysis of Critical Control Point (HACCP) and recall systems for food products (excluding meat, poultry, egg and dairy products). KFDA also regulates non-food related products, including cosmetics, vaccines, blood products, medical devices and radiation-emitting products.

KFDA is committed to improving the quality of life, maintaining high standards of living and ensuring the public's welfare. To support its science-based regulatory decisions, KFDA oversees the National Institute of Toxicological Research, which utilizes in vitro and in vivo analytical methods focused on the research and development of effective testing methods. KFDA headquarters in Seoul has two bureaus encompassing six departments. Two of the departments are dedicated exclusively to food related issues. KFDA headquarters also oversees six regional KFDA offices. KFDA publishes its food-related regulations, including the Food Code, Food Additive Code, Labeling Standards for Food et al, Labeling Standards for Recombinant Food, Guidelines for Safety Assessment for Recombinant Food, functional food regulations, etc., on its website: http://www.kfda.go.kr.

1. Food Code

The Food Code stipulates standards and specifications for manufacturing, processing, usage, cooking, storage of food and equipment, containers and packaging for food products. It specifies the standards for maximum residue levels of agricultural chemicals, antibiotics, synthetic antibiotics, hormones, radioactive ray standards, testing methods, etc. The Food Code contains general standards and specifications governing food products and individual standards and specifications for 124 food categories, delineated into 19 groups. The revision issued on April 1, 2004 includes new Maximum Residue Limits (MRLs) and modifications of MRLs, antibiotic residual standards, etc. The revision made on May 24, 2004 expanded the list of food products for which irradiation is permitted. The Code was last updated July 16, 2004.

2. Food Additive Code

The Food Additive Code defines standard specifications for individual food additives and usage standards. As of July 2004, the Food Additive Code listed standards for 415 types of chemical synthetics, 193 types of natural food additives, and 7 types of mixed food additives. Korea utilizes a "positive list" system for food additives meaning any food additive or its

usage not listed in the code is prohibited. The July 2004 version is the latest edition of the Code.

3. Labeling Standards for Food et al.

"Labeling Standards for Food et al." aims to promote the sanitary treatment of food products, et al., and to provide accurate information to consumers. The labeling standards for food, food additives and packaging are based on Article 10 of the Food Sanitation Act. The revision, dated July 2000, introduced the principal display panel labeling requirement, the labeling criteria for organic products, etc., and removed the food category labeling requirement for the majority of food products. The latest revision in March 2003 introduced the labeling requirements for 11 food products that could be considered as allergens. The draft revision, announced June 4, 2004, proposed to require listing all ingredients on the product label, "high caffeine content" declaration, etc. See Section II for details.

4. Labeling Standards for Recombinant Food (i.e., Labeling standards for processed food products containing ingredients enhanced through biotechnology)
In August 2000, KFDA released the Labeling Standards for Recombinant Food. Starting July 13, 2001, mandatory labeling went into effect for 27 items. The standards require labeling of processed food products and unprocessed corn or soybeans used for further processing with 3 percent or higher GMO corn or soybean content. See Section II for details.

5. Functional Food Code

The Functional Food Code was established on January 31, 2004. The Code contains general standards and specifications governing functional food, and individual standards and specifications for 32 categories. A food product that meets the criteria of one of 32 defined categories is permitted to carry the efficacy claim. Anyone wishing to export a functional food that is not one of 32 categories specified in this Code can apply to KFDA for: 1) recognition of raw materials that have specific health function (efficacy); and, 2) recognition of the new category. Details about recognition procedures, required documents, etc., are provided on the KFDA website at www.kfda.go.kr. However, it is available only in the Korean language.

C. Ministry of Agriculture & Forestry:

The Ministry of Agriculture & Forestry (MAF) is responsible for establishing regulations and standards related to agricultural products, including livestock and dairy products. Several agencies within MAF are responsible for issuing and enforcing regulations. The National Veterinary Research & Quarantine Service (NVRQS) is responsible for implementing regulations pertaining to both domestic and imported animals and livestock products. The National Plant Quarantine Service (NPQS) is responsible for implementing regulations pertaining to plants. The National Agricultural Product Quality Management Service (NAQS) is responsible for setting quality standards and grades for agricultural products, such as organic standards for agricultural produce, and enforcing country of origin marks. In 2000, MAF designated NAQS as its official inspection agency for testing of GMO products. The primary role of the Rural Development Administration (RDA) is research and development of new agricultural technologies and extension work. RDA is pro-biotechnology and is actively pursuing GMO research for several products common in the Korean diet. Given its technical expertise, RDA is the technical advisor on MAF policy toward GMO products. Starting March 2001, RDA began inspecting GMO products for one year and transferring its technical expertise to NAQS. Since March 2002, NAQS has fully taken over the responsibility of GMO inspection, including random sampling of products from retail markets and testing for GMO content. In 2001, MAF established the "GMO Task Force Team," which oversaw labeling enforcement for unprocessed GMO commodities (soybeans, corn, soybean sprouts, and potatoes), to achieve smooth enforcement of new GMO labeling requirements. In 2002,

however, the team was disbanded and the Food Industry Division, MAF took over the function. In 2003, MAF established a new division, Consumer Safety Division, responsible for GMO labeling and consumer policy, to meet consumers' high expectations for safe agriculture and livestock products.

1. National Veterinary Research & Quarantine Service

The National Veterinary Research & Quarantine Service (NVRQS) provides effective sanitary control of animal origin products from farm to table. NVRQS was established August 1, 1998, when the National Animal Quarantine Service and the National Veterinary Research Institute were merged. NVRQS is responsible for setting and implementing standards and specifications and labeling requirements for meat, poultry, eggs, and dairy products in accordance with the Livestock Product Processing Control Act. These standards and specifications apply to both domestically produced and imported food products. NVRQS is responsible for operating HACCP and recalls for meat, poultry, eggs and dairy products. NVRQS headquarters, in Anyang, has three departments and fifteen divisions. NVRQS has five regional offices with 14 district offices.

2. National Plant Quarantine Service

The purpose of the National Plant Quarantine Service (NPQS) is to prevent the introduction of harmful weeds, pests and disease originating from imported plants, fruits and vegetables. NPQS conducts a pest risk analysis and determines the appropriate eradication method for detected pests. NPQS sets and enforces quarantine requirements for imported plants, fruits and vegetables. NPQS headquarters, in Anyang, has five divisions and five regional offices with 21 district offices located in major Korean cities and ports.

3. Rural Development Administration

The Rural Development Administration (RDA) is responsible for developing the rural sector and administering policies on research and development, extension service, and training for farmers.

Under RDA there are eight research institutes, and the Korea National Agricultural College. The research institutes include:

National Institute of Agricultural Science and Technology,

National Institute of Agricultural Biotechnology,

National Institute of Agricultural Engineering,

National Institute of Highland Agriculture,

National Institute of Subtropical Agriculture,

National Livestock Research Institute,

National Horticultural Research Institute, and

National Institute of Crop Science

The National Institute of Agricultural Biotechnology (NIAB) is developing eighteen biotech-enhanced agricultural commodities with 45 varieties. Included are rice, chili (red pepper), potato, Chinese cabbage, cabbage, Perilla seed, tomato, apple, watermelon, cucumber, chrysanthemum, swine, chicken, etc. NIAB has been doing field trials of herbicide resistant rice and virus resistant potatoes for years and is planning to commercialize of those crops in the next four or five years. The institute is also developing GMO detection testing methods and conducting risk assessment of GMO crops for environmental release on a voluntary basis. NIAB will continue to conduct mandatory environmental risk assessments of biotech crops when the Act on Transboundary Movement, Etc., of Living Modified Organisms (LMO Act), the enforcement legislation of the Bio-safety Protocol, goes into effect.

4. National Agricultural Product Quality Management Service

The National Agricultural Product Quality Management Service (NAQS) is responsible for setting quality standards and grades for agricultural products, enforcing country of origin marks and GMO labeling requirements in the marketplace, and accrediting certifiers of non-processed organic produce. NAQS is the designated official inspection agency for unprocessed GMO commodities. NAQS collects samples from retail markets and tests products for GMO content with testing methods developed by RDA.

5. Acts, Regulations, Guidelines, etc., Governed by MAF or its Agencies Korean language text is available on the MAF's website: http://www.maf.go.kr.

(1) Livestock Processing Control Act

This Act aims to promote the sound development of the livestock industry and to improve public health by ensuring sanitary treatment and quality improvement of livestock products. To this end, the Act specifies requirements for the slaughter and treatment of livestock and the processing, distribution and inspection of livestock products. The Act is the legal basis for setting health standards provided in the Livestock Code (excluding antibiotic standards for meat, poultry and dairy products governed under the Food Sanitation Act).

- (2) Presidential Decree to the Livestock Product Processing Control Act
 The Presidential Decree aims to establish matters delegated by the Livestock Product
 Processing Control Act and matters necessary to enforce the Act.
- (3) Ministerial Ordinance to the Livestock Product Processing Control Act
 The Ministerial Ordinance aims to establish matters delegated by the Livestock Product
 Processing Control Act and the Presidential Decree thereof, and matters necessary for the
 enforcement of the Act and the Decree. The ordinance establishes the basics needed to
 conduct livestock product business and the relevant penalties, for non-compliance. It also
 provides samples of forms needed to conduct such business.

(4) Livestock Code

The Livestock Code provides health standards for meat, poultry and dairy products, such as microorganism standards, criteria and standards for livestock products, etc. (excluding antibiotic standards which are defined in the Food Code under the Food Sanitation Act). The current Livestock Code is drawn from the 1996 Food Code. The December 2003 version is the latest edition of the Code.

(5) Livestock Epidemics Prevention & Control Act

The Livestock Epidemics Prevention & Control Act aims to contribute to the development of the livestock industry and to improve public health by preventing the outbreak and spread of livestock epidemics. This Act focuses on live animals, whereas the Livestock Processing Control Act focuses on livestock products.

- **(6) Presidential Decree to the Livestock Epidemics Prevention & Control Act**The Presidential Decree aims to establish matters delegated by the Livestock Epidemics Prevention & Control Act and matters necessary to enforce the Act.
- (7) Ministerial Ordinance to the Livestock Epidemics Prevention & Control Act
 The Ministerial Ordinance aims to establish matters delegated by the Livestock Epidemics
 Prevention & Control Act and the Presidential Decree thereof, and matters necessary for the
 enforcement of the Act and the Decree.

(8) Import Health Requirements for Various Animals

Live animals and animal products should be in accordance with the standards as specified by the relevant MAF provisions issued through the Animal Health Division (AHD). AHD sets regulations and the National Veterinary Research & Quarantine Service (NVRQS) enforces them. Korea's health requirements for livestock and products can be accessed in English through the website of the Food Safety & Inspection Service (FSIS) of the U.S. Department of Agriculture at:

http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OFO/export/KOREASO.htm

(9) Labeling Standards for Livestock Products

This set of standards aims to promote the sanitary and seamless processing and control of livestock products et al. It is required for providing accurate information to consumers by defining the labeling standards for livestock products and containers, equipment, packaging and stamping colorings based on Article 6-1 of the Livestock Processing Control Act. The January 2004 version is the latest edition.

(10) Plant Protection Act

The Plant Protection Act aims to contribute to the safety and promotion of agriculture and forestry production by establishing quarantine regulations for imported/exported and domestic plants, and for the prevention and eradication of destructive animals and plants.

(11) Presidential Decree to the Plant Protection Act

The Presidential Decree aims to establish matters delegated by the Plant Protection Act and matters necessary to enforce the Act.

(12) Ministerial Ordinance to the Plant Protection Act

The Ministerial Ordinance aims to establish matters delegated by the Plant Protection Act and the Presidential Decree thereof, and matters necessary for the enforcement of the Act and the Decree.

(13) Import Plant Inspection Guideline

The Import Plant Inspection Guideline defines consistent and effective inspection procedures for imported plants and plant materials by establishing specific principles for the inspection and disposition of imported plants as delegated to the Director General of the National Plant Quarantine Service (NPQS) in the Plant Protection Act, the Presidential Decree to the Act and the Ministerial Ordinance to the Act.

(14) Agricultural Products Quality Control Act

The Act, passed by the National Assembly in December 1998, includes provisions governing GMO agricultural products and labeling, country of origin marks, etc. The Act gives a legal basis for MAF to require labeling of unprocessed GMO commodities for the purpose of providing proper product information to consumers.

(15) Presidential Decree to the Agricultural Products Quality Control Act

The decree aims to establish matters delegated by the Agricultural Products Quality Control Act and matters necessary to enforce the Act. In June 1999, the decree was revised to add provisions governing the labeling of unprocessed GMO commodities. The latest revision, made on July 15, 2002, adds another option for labeling a product as "May Contain GMO."

(16) Guideline for Labeling of Genetically Modified Agricultural Products

The Guideline, proposed on December 1, 1999 and finalized on April 22, 2000, provides details on labeling requirements for unprocessed GMO commodities, including a list of commodities subject to GMO labeling, labeling methods, etc. According to the guideline, four

unprocessed GMO commodities – soybean, bean sprout, corn, and potato – shall require labeling if three percent or more of the shipment contains a biotech-enhanced component. The guideline calls for GMO labeling for soybean, bean sprout, and corn starting in March 2001, and for potato starting in March 2002.

(17) Sustainable Agriculture Promotion Act

The Act aims to promote environmentally sustainable agriculture ("organic") by introducing production methods and techniques to protect the environment, by reducing environmental pollution related to agriculture, and by encouraging the adoption of sustainable agriculture.

(18) Presidential Decree to the Sustainable Agricultural Promotion Act

The Presidential Decree aims to establish matters delegated by the Sustainable Agricultural Promotion Act and matters necessary to enforce the Act. The June 2001 version is the latest edition.

(19) Ministerial Ordinance to the Sustainable Agricultural Promotion Act

The Ministerial Ordinance aims to establish matters delegated by the Sustainable Agricultural Promotion Act and the Presidential Decree thereof, and matters necessary for the enforcement of the Act and the Decree. This provides quality control standards for four types of sustainable agricultural produce: organic produce, transitional organic produce, nopesticide produce, and low pesticide produce. This Act also provides requirements for organic certifying agents, certification, etc. The May 2003 version is the latest edition.

(20) Guideline for Country of Origin (COO)

The guideline aims to protect consumers and agricultural producers from mislabeled products. COO labeling of domestic agricultural products and raw materials used in domestically processed agricultural products is required under Article 17 of the Agricultural & Fishery Products Quality Control Act and Articles 38 to 40 of the Presidential Decree of the Act. COO labeling of imported agricultural products is required under Article 53 of the Presidential Decree of the Foreign Trade Act. The November 2000 version is the latest edition.

(21) Seed Industry Act

The Act, implemented December 31, 1997 and revised January 26, 2001, brought Korea into compliance with its WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) and OECD commitments related to the planting seed trade. The major impact of the Act is the protection of intellectual property rights. The Act did not liberalize imports of major staple crop seeds.

The Seed Industry Act combined provisions of the Seedling Management Act, which governed the vegetable seed sector, and the Major Agricultural Seed Act, which governed the seed sector for major field crops. The Presidential Decree and Ministerial Ordinance to the Seed Industry Act became effective December 31, 1997 and January 24, 1998, respectively. On June 1, 2000, the seed fund provision of the Seed Industry Act was deleted. The January 2001 version included a revision of Article 165, which strengthened the management of genetic resources at the national level.

For more information regarding general regulations of planting seed, contact:

Dr. Keun Jin CHOI
National Seed Production & Distribution
Rural Development Administration
Ministry of Agriculture and Forestry
Phono: 92, 31, 446, 2432

Phone: 82-31-446-2432

Fax: 82-31-448-1216

e-mail: <u>nspd074@chollian.dacom.co.kr</u>

D. Ministry of Maritime Affairs & Fisheries

The Ministry of Maritime Affairs and Fisheries (MOMAF) was established in 1994 with the merging of the National Maritime Affairs Administration and the National Fisheries Administration. MOMAF is responsible for making policies and plans for maritime affairs and fisheries, maintaining facilities and materials, and instructing all operations related to maritime affairs and fisheries.

Under the jurisdiction of the MOMAF Minister are various sub-organizations such as:

National Fisheries Research & Development Institutes, Fisheries Research Institute, National Oceanographic Research Institute, National Fisheries Products Quality Inspection Service, Regional Maritime Affairs and Fisheries Office, Differential Global Positioning System Central Office, Fisheries Patrol Vessel Management Office, and Marine Accidents Inquiry Agency.

On December 31, 2002, MOMAF introduced a labeling requirement for three fishery items enhanced through biotechnology: Rainbow trout, Atlantic salon, and Mud loach. See Section II for details. This labeling requirement will be mandated when the LMO Act, the enforcement legislation of the Bio-safety Protocol, goes into effect. The National Fisheries Products Quality Inspection Service (NFPQIS) has been designated as the enforcement agency for biotech labeling of fishery products. NFPQIS is also charged with inspection of fishery products, whether produced in Korea or imported.

1. Fishery Products Inspection Act

The Act aims to promote quality improvement and standardization of fishery products through inspection. It is the legal basis for the fishery inspection work conducted by NFPQIS.

2. Presidential Decree to the Fishery Products Inspection Act

The Presidential Decree provides provisions for implementing the Fishery Products Inspection Act.

3. Ministerial Ordinance to the Fishery Products Inspection Act

The Ministerial Ordinance to the Fishery Products Inspection Act prescribes the articles delegated by the Fishery Products Inspection Act and the Presidential Decree, and the necessary implementing articles, including the detailed standards that fish and products must meet.

E. Ministry of Commerce, Industry, and Energy

The Ministry of Commerce, Industry, and Energy (MOCIE) is mainly responsible for establishing trade policy related to export and imports. As such, MOCIE released proposed legislation based on its interpretation of the Cartagena Bio-safety protocol October 22, 2000. This legislation, the "Act on Transboundary Movement, Etc., of Living Modified Organisms (LMO Act)," was finalized March 28, 2001. In June 2002, MOCIE announced the draft proposals of the Presidential Decree and the Ministerial Ordinance to the LMO Act to establish

matters necessary for the implementation of the Act. MOCIE aims to finalize the draft proposals within 2004 so Korea can be prepared for enforcement of the Bio-safety Protocol.

1. Act on Transboundary Movement, Etc., of Living Modified Organisms (LMO Act) The Act aims to promote international cooperation and enhancement of people's livelihood by establishing details necessary for implementing the Cartagena Protocol on Bio-safety and for pursuing the ensurement of safety in the field of development, production, import, export, marketing, etc., of living modified organisms. This is to address, in advance, any risk that may be imposed upon the conservation and sustainable use of biological diversity and human health that may come from living modified organisms. This Act provides guidance on import approval, mandatory risk assessment, labeling, etc., of living modified organisms (LMO or GMO commodities). See Attaché Report KS 1029 for details.

2. Presidential Decree of the LMO Act

This Decree aims to stipulate the provisions delegated by the LMO Act and the provisions deemed necessary to implement the Act. This Decree includes roles of relevant government agencies, procedures for the import, production, export notification, transit report, etc., of LMOs, procedures for designating the risk assessment and specialized review agencies, labeling and handling requirements, the creation and operation of Bio-safety clearing house, etc.

3. Ministerial Ordinance of the LMO Act

It aims to stipulate the provisions delegated by the LMO Act and its Presidential Decree and the provisions deemed necessary to implement the Act and Decree. This Ordinance includes document requirements for import approval of LMOs, safety assessments, environmental risk assessments, production approval, etc.

SECTION II. LABELING REQUIREMENTS (GENERAL/NUTRITION/ORGANIC/HEALTH CLAIMS)

Labeling requirements change frequently and importers must abreast of changing regulations. In addition to the following requirements, country of origin labeling is required on food products. Korean language stickers can be applied at the port of entry.

A. Labeling Standards for Food et al (Administered by KFDA)

In June 1998, KFDA was legally delegated authority for food labeling standards. The Food Safety Division, KFDA, is responsible for establishing the labeling standards for food products. KFDA regional offices enforce the labeling standards. Provincial government health officials also have the authority to enforce the labeling standards.

With the exception of livestock products, which are regulated by the MAF, all imported food products are required to be labeled with the necessary information in the Korean language. Stickers may be used instead of manufacturer-printed Korean language labels for general food products. The sticker should not be easily removable and should not cover the original labeling. For functional food items, however, stickers are not permitted. Manufacturer printed Korean language labels must be used on such products.

<u>Labels should have the following inscriptions printed in letters large enough to be readily legible:</u>

- **(1) Product Name:** The product name should be identical to the product name declared to the licensing/inspection authority.
- **(2) Product type:** This is mandatory for specially designated products, such as teas, health supplementary foods, etc.
- (3) Importer's name and address, and the address where products may be returned or exchanged in the event of defects.
- **(4) Manufactured date month, and year:** This is mandatory for specially designated products, such as lunch box, sugar, liquor, and salts. For liquors, a manufacture number (lot number) or bottling date can substitute for the manufactured date.
- **(5) Shelf life:** Food products should identify the manufacturer-determined shelf life. If various kinds of products are packaged together, the shelf life expiration date of the product with the shortest life should be noted on the label.
- **(6) Contents:** Weight, volume or number of pieces. If the number of pieces is shown, the weight or volume must be indicated in parentheses.
- (7) Ingredient(s) or raw material(s) and a percent content of the ingredient(s): The name of the major ingredient must be included on the label as well as the names of at least the next four principle ingredients. These should be listed with the highest percentage ingredient first, followed in descending order by the others. Artificially added purified water does not count as one of the five major ingredients. Some food additives required by the Labeling Standards for Food et al. need to be indicated on the label. Besides the top five ingredients and food additives, an indication of food items known to be food allergens is mandatory. Food items considered as food allergens include eggs, milk, buckwheat, peanuts, soybeans, wheat, mackerel, crab, pork, peaches and tomatoes. Any food product containing

one or more of the above 11 items, as a raw ingredient (ingredients), must indicate the name (names) on the Korean language label.

- **(8) Nutrients:** Only special nutritional foods, health supplementary foods, bread and bread loaf, noodles (cooked noodle, fried noodle, gelatinized dry noodle, and improved cooked noodle), retort foods, products for which nutritional labels are sought, and products for which a nutrient emphasis mark is desired are subject to nutritional labeling.
- (9) Other items designated by the detailed labeling standards for food et al.: This includes cautions and standards for use or preservation (e.g., drained weight for canned products, radiation-processed products, etc.).

The revision, dated July 2000, introduced the principal display panel labeling requirement, the labeling criteria for organic products, etc., and removed the food category labeling requirement for the majority of food products.

Please note the principal display panel must contain the product name, product type, and content information. If this is not feasible, such information shall be provided in a Korean language sticker using a 12-point or larger font size.

<u>Cases where the above application of the labeling requirements is exempted are as</u> follows:

- (1) Agricultural products such as grains, fishery items, such as whole frozen fish, and fruits, that are loose, in a container or packaging, etc.
- (2) Foods, etc., to be used for manufacturing or cooking for a company's own use. (Documents that show such intent need to be provided.) The package for such foods shall be labeled with the name of the manufacturer and manufacture date or shelf life.
- (3) Products imported for the purpose of acquisition of foreign currency, under the provisions of Article 34 of the Ministerial Ordinance to the Foreign Trade Act.

<u>Nutritional labeling requirements</u>: These requirements are specified in the Labeling Standards for Food et al. As of now, nutritional labeling is optional for most food products. Korea only requires nutritional labeling for the following:

- (1) Special nutritional food or health supplementary food,
- (2) In the event that specific nutrients are emphasized (e.g., if a product is labeled as "calcium added yogurt," the content of the calcium must be labeled),
- (3) If nutritional labeling is desired,
- (4) Bread and bread loaf, noodles (cooked noodle, fried noodle, and improved cooked noodles only), and retort foods

If a product does not fall under one of the above four categories, a nutritional label is not required.

On June 4, 2004, KFDA announced a draft revision of the Labeling Standards for Food et al. In that draft revision, KFDA proposed to extend nutrition labeling to candy, chocolate, jam, fruit and vegetable juices, etc. The draft revision also proposed to introduce a "high caffeine

content" declaration for food containing a high level of caffeine. Once this draft revision is finalized, Post will submit a voluntary GAIN report so indicating.

Regarding health claims, Korea currently does not allow health claims on food product labels. However, the efficacy claim is permitted for food products that meet the criteria of functional foods.

<u>Functional food labeling requirements</u>: Labeling Standards for Functional Food was established January 31, 2004. In accordance with those standards, a manufacture's printed Korean language label must on the product. It should have the following inscriptions, in addition to those required for general food products listed above: 1) functional food to be indicated; 2) information on the efficacy claim; 3) intake direction and cautions; 4) statement containing that the product is not a pharmaceutical product that prevents or heals disease; and, 5) other points as required in the detailed labeling guidelines for functional food.

<u>Organic labeling requirements for processed products</u>: These labeling requirements are now specified in the Labeling Standards for Food et al. The labeling standards for organic products are:

- (1) Organic raw materials of imported food products shall be equal to or better than the quality standards specified in Article 16, Paragraph 2, of the Environmental Agricultural Promotion Act, and Article 7, Annex 1, of the Enforcement Regulations of the Act.
- (2) If organic raw materials of imported food products are not subject to the quality standards specified in the above Korean regulations, such products shall meet the relevant quality standards of the exporting country.
- (3) Organic and non-organic agricultural products shall not be used in a mixture as one raw material.
- (4) Raw materials not included on the list of raw materials permitted for use in the manufacture or processing of organic food products (See section IV) shall not be used. In accordance with the Labeling Standards for Food et al., "raw material" is defined as a material, except for purified water purposely applied to the product, that is used for the manufacturing, processing or cooking of food or food additives and that are contained in the final product.
- (5) Irradiated raw materials shall not be used.
- (6) Genetically modified foods or food additives shall not be used.
- (7) The container or package used for a food may be recycled or made of biodegradable material.
- (8) The determination as to whether an imported food meets the standards specified in (1) through (7) above may be based on a certificate issued by an organization which satisfies the qualifications to be a certifying entity under the relevant regulations of:
- a) the exporting country, or
- b) a reliable organization certified by a recognized international body, such as IFOAM (International Federation of Organic Agricultural Movements).

For such determination, KFDA has completed the review of the U.S. National Organic Program (NOP) and concluded that the U.S. organic standards are equivalent to Korean

organic standards. As a result, KFDA recognizes USDA-accredited certifying agents as foreign organic certifiers able to issue organic certificates for imported food products. To date, KFDA has recognized 106 foreign organic certifiers. Of those, 54 are USDA-accredited certifying agents located in the United States.

For USDA-accredited certifying agents located outside the United States, KFDA accepts their organic certificates issued for U.S. products that were produced, manufactured, handled, etc., by U.S. organic farms or U.S.-based companies. Based upon KFDA's Labeling Standards for Food et al., imported organic food products must be certified by certifiers accredited by the exporting country's government. Therefore, KFDA accepts certificates issued by USDA-accredited certifying agents located outside the United States for U.S.-origin organic products but does not recognize those agents' USDA accreditation as the basis for acceptance of their certificates issued for non-U.S. origin products.

<u>Labeling</u>: Labeling may be done in the following manner depending on the content of organic agricultural ingredients in a food product.

- (1) 100%: when the finished food product does not contain any other food or food additive except for organic agricultural ingredients, the label "100% organic agricultural product" or similar labels may be used.
- (2) Not less than 95%: when no less than 95 percent of raw materials contained in the finished food product are organic agricultural ingredients, the term "organic" or similar terms may be used as a part of the product name and stated on the main labeling panel of the container or package; and the name, seal and logo of the organization that certified the organic agricultural produce used in the product, as well as other certification information, may be stated. In this case, the content of the organic agricultural ingredients shall be stated in percentage in the labeling section for raw material names.
- (3) Less than 95% but more than 70%: when 70 percent or more but less than 95 percent of raw materials contained in the finished food product are organic agricultural ingredients, the term "organic" or similar terms may be stated on a labeling surface of the container or package other than the main labeling panel. In this case, the content of the organic agricultural ingredients shall be stated in percentage in the labeling section for raw material names.
- (4) Others: when a food not included in (1) through (3) above includes organic agricultural produce, the term "organic" or similar terms may be used as a part of the names of such ingredients within the labeling section for raw material names. In this case, the content of organic agricultural ingredients shall be stated in percentage in the labeling section for raw material names.

<u>Documentation Requirements to Qualify for Imported Organic Food Products</u>

The following two documents should be presented to regional offices of the KFDA when submitting the import application for organic food products for import clearance.

- (1) A copy of an organic certificate issued by the USDA-accredited certifying agent. The certificate must include following information.
- Name, address, and phone number of the certifying agent;
- Types of organic food the operation (grows, manufactures, processes, produces, etc.) is certified by the certifying agent to produce, process and/or handle, along with the company name, address, and effective date (or renewal date) of certification.

(2) An original ingredient statement (a list of all ingredient names) issued by the manufacturer (only required for organic food products made of mixed ingredients) that includes the office/department/division name, name and signature of the issuer.

Please note that a "transaction certificate" is no longer required for imported organic food products. Contact information for the KFDA divisions responsible for labeling is:

For organic label Imported Food Division

Food Safety Bureau, KFDA # 5 Nokbeon-dong, Eunpyung-ku Seoul, Korea 122-704 Phone: 82-2-380-1733/34

Fax: 82-2-388-6392

For nutrition label Nutrition Evaluation Division

Office of Food Evaluation # 5 Nokbeon-dong, Eunpyung-ku Seoul, Korea 122-704

Phone: 82-2-380-1678/80 Fax: 82-2-380-1358

B. Labeling Standards for Livestock Products (Administered by MAF)

A business enterprise or person wanting to make an import declaration, in accordance with the provision of the Article 6-1 of the Livestock Processing Control Act, should indicate (label) the following:

- (1) The labeling requirement is in accordance with Article 3 of the Labeling Standards for Livestock Products:
- (a) Product name
- (b) Type of processed livestock product
- (c) Name and address of company
- (d) Manufacturing date month and year (only designated products are subject to this category)
- (e) Shelf life
- (f) Content
- (g) Ingredient or raw material and the content of the ingredient (if a certain ingredient is used in the product name or as a part of the product name);
- (h) Nutrient (only designated products are subject to this category);
- (i) Other items specified in Appendix Table 1 of the Labeling Standards for Livestock Products, according to the "Detailed Labeling Standards for Livestock Product et al."

Labels should be in Korean language and written in ink, engraved or stamped that cannot be erased. However, registered trademarks in foreign language (according to the Korean Trademark Law) and Chinese characters can be written next to the Korean writing, so consumers can better understand the labeling.

(2) Exemption from application: Imported livestock products may be exempt from the Korean language labeling if it belongs to one of the following categories:

- (a) Carcass
- (b) Large packaged products (bulk type), limited only to raw materials to be repackaged prior to sale
- (c) Raw materials for manufacturing processed livestock products (i.e., frozen turkey to be used in manufacturing sausage)
- (d) Products permitted to be imported for the purpose of earning foreign currency per the Foreign Trade Management Regulations;

The January 2004 revision is the latest edition.

Contact information for the NVRQS division responsible for livestock product labeling follows:

Quarantine Inspection Division

Department of Inspection of Livestock Products National Veterinary Research & Quarantine Service #480 Anyang 6-dong, Manan-ku, Anyang-shi Kyunggido, Korea

Phone: 82-31-467-1744/42; Fax: 82-31-467-1717

C. Labeling Regulations for Non-Processed GMO products (Administered by MAF)

On April 22, 2000, MAF issued final guidelines for labeling of unprocessed GMO commodities. Starting March 1, 2001, mandatory labeling went into effect for three unprocessed GMO commodities – soybean, bean sprout, and corn – if three percent or more of the shipment contains biotech-enhanced ingredients. In March 2002, MAF extended its labeling requirement to include unprocessed GMO potato.

Labels shall be in accordance with the following:

- (1) For raw GMO agricultural commodities, it shall be labeled as "Genetically Modified XX (a name of agricultural product)."
- (2) For agricultural commodities containing a GMO component, it shall be labeled as "Containing Genetically Modified XX (a name of agricultural product)."
- (3) For agricultural commodities that possibly may contain a GMO agricultural component (but the importer is not certain), the agricultural commodity shall be labeled as "It may contain Genetically Modified XX (a name of agricultural product)."
- (4) For agricultural commodities that are 100-percent GMO free, the agricultural commodity may be labeled as "Non-GMO" or "GMO Free" on a voluntary basis. Note: The three percent maximum threshold allowance does not apply to such commodities.

See Attaché Report KS1004 for details.

The National Agricultural Product Quality Management Service (NAQS) is the designated official inspection agency for unprocessed GMO commodities. Since March 2002, NAQS has taken full responsibility for GMO testing of raw soybeans, corn, bean sprout, and potato samples collected from retail markets.

Contact information for the MAF division responsible for unprocessed GMO commodity labeling follows:

Consumer Information and Food Safety Division

Ministry of Agriculture & Forestry # 1 Choongang-dong, Kwacheon City Kvungqi-do, Korea 427-760

Phone: 82-2-2110-4349 or 4350; Fax: 82-2-503-7277

D. Labeling Standards for Recombinant Food (Administered by KFDA)

In August 2000, KFDA announced the Labeling Standards for Recombinant Food (labeling standards for processed food products containing ingredients enhanced through biotechnology).

Effective July 13, 2001, the KFDA requires labeling of processed food products and unprocessed agricultural food products for further processing that contain ingredients enhanced through biotechnology.

- (1) Processed food products shall be labeled when:
- (a) The primary ingredient is subject to MAF biotech labeling requirements (presently soybeans, corn and bean sprouts only, and not potatoes),
- (b) The GM ingredient is one of five major raw materials used in the product, and
- (c) Recombinant DNAs or foreign proteins are still present in the final product.
- (2) An unprocessed agricultural commodity to be further processed into a food product shall be labeled when:
- (a) The agricultural commodity is subject to MAF biotech labeling requirements as it exceeds the threshold allowance for a GM component.
- (3) Labels shall contain the following terminology:
- (a) "Recombinant Food" or "Food Containing Recombinant XX" (e.g., "Food Containing Recombinant Corn") shall be used for a food known to contain a 100 percent biotechenhanced ingredient. The text is to be indicated on the principle display panel in such a way that the consumer may easily recognize the label.
- (b) "Recombinant" or "Recombinant XX" (e.g., "Recombinant Corn") shall be used for a food known to contain a biotech-enhanced ingredient. The text is to be indicated in parentheses beside the name of the GMO ingredient listed as a raw material of the food.
- (c) "May contain Recombinant XX" shall be used for a product if an exporter or importer is not sure whether it contains a GMO ingredient or not.
- (4) Colors used to label the recombinant nature of the food shall be clearly distinguishable from the color of the container or package. Indelible ink, a stamp, brand, etc., shall be used so that the consumer may easily find the label.

- (5) Non-detachable stickers may be used for imported foods or food additives. Indelible ink, stamp or brand, etc., shall be used.
- (6) The terminology "Non-GMO" and "GMO Free" is strictly prohibited for use on labels of processed foods.
- (7) No label shall be affixed to the product if the processed food is made using non-GMO ingredients or if one or more of top five major ingredients contain less than three percent GMO component. (In this case, documents listed below shall be provided.)
- D.1. Korean Food and Drug Administration's (KFDA) documentation requirement guidance for exemption to GMO labeling requirements of processed foods follows. (Note: The KFDA website is the source of this information).
- (1) Identity Preserved (IP) handling certification for raw corn or soybeans and certification (or a statement) for the finished product:
- (a) IP handling certification requirements for raw corn and soybeans separate certification shall be issued at designated points from farm to the processing plant. Certification can be issued by any private entity responsible at each designated point in the process. Certification is required at the following points: seed purchase, crop production, crop storage, segregation, delivery, and shipping. KFDA accepts a photocopy of IP handling certificates.
- (b) IP handling certification requirements for a finished product: Certification (or a statement) issued by the manufacturer, processor, seller or supplier of the final product shows that non-GMO ingredients are used in the manufacture of the product, or that the product contains less than three percent GMO ingredients (if one of the top five ingredients is corn or soybean). KFDA requires the original document (*no copy*).
- (2) Government-issued certification equivalent to IP handling certification: In lieu of the IP handling certificates noted in (a) above, KFDA accepts one of the following government-issued documents.
- (a) For a country that does not produce or sell GMO crops or a particular GMO food, a government-issued certificate stating that the GMO agricultural crop or particular GMO food in question is not produced or sold in that country is acceptable. If the government does not submit the certification on behalf of the exporting country, the importer will be required to submit the original certificate with the first shipment of a product, with a photocopy of the original certificate with each subsequent shipment of the same product.
- (b) For raw corn or soybeans, a government-issued certificate that verifies the presence of less than three percent GMO component.
- (c) For processed food products, a government-issued certificate that states there is no presence of DNA or foreign protein. For example, if any government agency, including state, federal, or regional office of the state or federal government, issues a letter or statement saying that there is no presence of recombinant DNA or foreign protein in the final product, the original copy of such a document would be sufficient.
- (d) A government-issued certificate that raw material used in the final product was handled under an IP program. In this case, documents covering IP handling at each point as identified in (a) above are required.

- (e) Other documents recognized by the government of the exporter or manufacturer as equivalent to IP handling certificates. For U.S. origin processed food products, a notarized self declaration stating that products do not contain GMO ingredients is also accepted by KFDA as one of documents to get exemption to GMO labeling requirements. However, the exporter/importer must submit IP documentation to KFDA in the event that random testing reveals the presence of GMO ingredients.
- (3) Test certificates: A test certificate issued by a domestic commercial laboratory, foreign government or foreign commercial laboratory is acceptable if it shows no presence of recombinant DNA or foreign protein in the final product. The original test certificate will be submitted to KFDA. At present, KFDA has not developed an official testing methodology. Further, KFDA has not yet developed a program for designating foreign or domestic laboratories for official GMO testing. Note: If the test shows a presence of GMO component, then either IP requirements outlined in (a) above must be met for to be exempt from labeling or a label must be affixed stating the product does contain a GMO component.
- (4) Stickering "It may contain GMO XX (a name of agricultural product)": If requirements of (a), (b) or (c) above cannot be met, the importer or exporter must apply a sticker on the product stating "It may contain GMO XX." Such stickers can be applied in Korea prior to Customs clearance.
- (5) Testing in Korea: If the imported product arrives without appropriate documentation, it can be tested in Korea prior to Customs clearance.

See Attaché Report KS 1046 for details.

Contact information for the KFDA division responsible for GMO labeling follows:

Imported Food Division

Food Safety Bureau, KFDA # 5 Nokbeon-dong, Eunpyung-ku Seoul, Korea 122-704

Phone: 82-2-380-1733/4; Fax: 82-2-388-6392

Please note that KFDA does not require biotech labeling for potato-based products. This requirement was supposed to go into effect July 2002 but was delayed as no biotech potato seed has been sold in the U.S. (the only alleged biotech potato producing country) since 2000. Commercial production ended in 2001. If KFDA considers requiring biotech labeling for potato-based products, KFDA will announce a list of potato-based products subject to the requirement and revise the current biotech labeling guidelines accordingly.

E. Labeling Regulations for Organic Agricultural Products - Sustainable Agriculture Promotion Act, (Administered by MAF)

On December 13, 1997, the Sustainable Agriculture Promotion Act was passed. In December 1998, the Presidential Decree and the Ministerial Ordinance of the Act were released with the aim to establish matters delegated by the Act and details needed to enforce the Act. These legislations were revised in January, June and July 2001 respectively.

In accordance with the above legislations, organic produce is classified into four categories: organic produce, transitional organic produce, no-pesticide produce, and low pesticide produce, and can be labeled accordingly. For imported organic agricultural produce, the product is required to get certification from an official certification agency recognized by MAF.

To date, MAF officially designated seven Korean certification agencies. No foreign entities have been designated. Unlike KFDA's labeling regulations for organic processed products, organic agricultural produce complying with the U.S. organic standards or international standards still needs certification from MAF's official certification agency to carry an "organic label" in the Korean market.

The Sustainable Agriculture Division, MAF, establishes the regulations for organic products. The National Agricultural Products Quality Management Service (NAQS) enforces these regulations.

Sustainable Agriculture Policy Division

Food Grain Production Bureau, MAF # 1 Choongang-dong, Kwacheon City Kyunggi-do, Korea 427-760 Phone: 82-2-2110-4314 or 4315

Fax: 82-2-507-2096

Quality Management Division

NAOS

310 Choongang-ro, Manan-ku Anyangshi, Kyunggi-do, Korea Phone: 82-31-446-0127

Fax: 82-31-446-0903

F. Liquor Labeling (Administered by Korea Tax Administration)

As of October 1, 2002, liquor products must have labels that distinguish liquors for onpremise, home consumption, discount stores and duty-free shops sales. The on-premise use does not require separate labels but the remaining three categories do.

- (1) The classification of usage must be indicated on the main label or supplementary label for imported liquor, and only on the main label for domestic products.
- (2) Liquors for consumption at home and discount store sale must be marked as "for home use" or "for discount stores" in white against a green or dark blue background. Printing the writing in a color that can be clearly distinguished from main label's background color and outlined with a box is also acceptable.

Liquors for "at home use" and "discount stores" must also have a statement that reads "Not allowed to be sold in restaurants and bars" on the main label or supplementary label.

G. Country of Origin (COO) - (Administered by MAF)

According to COO labeling guidelines, many agricultural products, including most imported products, must be labeled by origin. Detailed labeling information is provided in the guideline for COO labeling. The National Agricultural Product Quality Management Service (NAQS) enforces COO requirements in the marketplace. As for imported products, the Korea Customs Service enforces COO requirements prior to Customs clearance.

Consumer Information and Food Safety Division

Agriculture Marketing Bureau, MAF # 1 Choongang-dong, Kwacheon City Kyunggi-do, Korea 427-760

Phone: 82-2-2110-4349 or 4350; Fax: 82-2-503-7277

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

"Standards & Specifications for Equipment and Container/Packaging" established by KFDA and printed in Chapter 6 of the Korean Food Code, includes general standards for equipment, container and packaging for food products and specifications for individual packaging materials.

The Ministry of Environment announced regulations in 1999 covering PVC shrink wrap packaging, which went into effect January 1, 2001.

SECTION IV. FOOD ADDITIVE REGULATIONS

Food Additive Code (Administered by KFDA)

The "Food Additive Code" guides the use of all additives in foods in Korea. As of July 2004, Korea had a positive list of 615 approved food additives. Food additives are grouped into three categories: (a) chemical synthetics, (b) natural additives, and (c) mixture substances. Most additives and/or preservatives are approved and tolerance levels are established on a product-by-product basis in Korea. This creates difficulties as tolerances can vary from product to product. Getting a new additive added to the approved list can be time consuming and troublesome. Even though there may be an established CODEX standard for a given food additive, if that food additive is not registered in the Korean Food Additive Code, or even if registered but usage in a certain food product is not specified, use of that food additive in the given food product is prohibited. This means that only food additives registered in the Korean Food Additive Code are allowed for use in food products, in accordance with the usage standards specified in the Food Additive Code.

The office responsible for approving food additives in KFDA is as follows:

Food Additives Evaluation Department

Korea Food & Drug Administration # 5 Nokbeon-dong, Eunpyung-ku

Seoul, Korea 122-704

Phone: 82-2-380-1687; Fax: 82-2-382-4892

SECTION V. PESTICIDE AND OTHER CONTAMINANTS (ANTIBIOTICS AND GROWTH HORMONES)

Three government agencies – the Korea Food & Drug Administration (KFDA), the Ministry of Agriculture & Forestry (MAF) and the Ministry of Environment (MOE) – handle pesticide related matters.

KFDA is responsible for regulating pesticide residues in foodstuffs, in accordance with the maximum residue levels (MRLs) set in the Food Code. As of July 2004, KFDA has set MRLs in foods for 347 pesticides. The MRLs are listed under Chapter 3 in the Food Code. The KFDA's English website (http://www.kfda.go.kr/eng/download/KoreaMRLsforPesticides.pdf) provides the latest MRLs in English. If an MRL is established in the Food Code for a given agricultural chemical, other tolerance levels, such as CODEX, etc., are not accepted. However, for agricultural chemicals where tolerance levels have not been established in the Korean Food Code, rules described below are applied.

- (1) The CODEX standards shall apply;
- (2) If the provision in (1) is not applicable, the lowest of the residue limits of the agricultural chemical in question specified for similar agricultural products shall apply to the agricultural product in which the agricultural chemical is detected (a grouping of similar agricultural products is provided in the Chapter 3 of the Korean Food Code);
- (3) If provisions in (1) and (2) are not applicable, the lowest of the residue limits of the agricultural chemical shall apply to the detected agricultural chemical.

MAF is responsible for the registration of pesticides, safety usage standards and notification of pesticides. All pesticides used in Korea should be registered with MAF.

MOE is responsible for testing pesticide levels in water, soil and agricultural products.

The Food Code also lists antibiotics and growth hormones approved for meat products in Chapter 3 of the code. It provides a list of permitted antibiotics and hormones and tolerance levels for each. The offices responsible for pesticides and contaminants are as follows.

Pesticide Residues Division

Korea Food & Drug Administration # 5 Nokbeon-dong, Eunpyung-ku Seoul, Korea 122-704

Phone: 82-2-380-1673~5

Fax: 82-2-380-1359

Food Contaminant Division

Korea Food & Drug Administration Division # 5 Nokbeon-dong, Eunpyung-ku Seoul, Korea 122-704 Phone) 82-2-380-1669~71

Fax: 82-2-380-1359

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS (CERTIFICATION)

A. Sanitary and Phytosanitary Certification Requirements – Animals, Meat, Plant, etc.

Sanitary and phytosanitary certificates issued by the exporting country's inspection authority are required for live animals, plants and meat products, such as beef, pork, poultry, etc. This requirement is in accordance with the Livestock Epidemics Prevention & Control Act, the Plant Protection Act, and the Livestock Processing Control Act, respectively.

For the United States, the U.S. Department of Agriculture (USDA), Animal & Plant Health Inspection Service (APHIS), issues sanitary and phytosanitary certificates for live animals and plants, while the USDA, Food Safety & Inspection Service (FSIS), issues health certificates for meat products.

Korea requires pre-approval of meat facilities, including slaughter plants, processors, warehouses, etc., prior to export of the product to the Korean market. Pre-approval is facilitated by registration with the FSIS and listing in the FSIS Meat, Poultry Inspection Directory. Further, it is advised that U.S. companies wanting to export meat products to Korea first verify that the supplying U.S. facilities are approved by Korea.

The "issuance date" of both health and phytosanitary certificates shall be prior to the "on-board date" listed on the Bill of Lading. The "inspection date" on a certificate must be prior to the departure date. To prevent unnecessary delay at the port of entry, the certificate "issuance date" should be prior to the departure date of shipments.

On December 23, 2003, in response to the finding of one positive case of BSE in Washington State, an animal that had been imported from Canada, Korea banned all ruminant animals and their products originating from the United States. Korea has similar bans on all ruminant products coming from 34 countries – 30 European nations, Japan, Israel, Canada and the United States. A total of 680 U.S. products have been banned due to the BSE situation. Only dairy products, hides and skins, semen of ruminant origin, fetal calf serum, porcine gelatin, porcine plasma powder, pet food without any ruminant ingredient in retail packages, tallow with an "insoluble impurity" of 0.15 percent or lower, and fish meal produced in a facility dedicated for producing only fish meal can be imported from approved plants. Korea has indicated its willingness to allow imports of the following products. However, details on certification, plant approval, etc., have yet to be completed. The products are: 1) Gelatin and collagen originating from hides and skins only; 2) Dicalcium phosphates free of protein and fat; and, 3) Hydrolyzed poultry protein for animal feed ingredients.

Korea suspended import inspection of U.S. poultry and poultry products, except for Specific Pathogen Free (SPF) hatching eggs and cooked products that have been processed (e.g. heat treated to kill the virus), beginning February 7, 2004, based on the report of the Avian Influenza (AI) outbreak in Delaware. The suspension placed on import inspection of U.S. poultry products was shifted to a ban February 24, 2004, after confirmation of the outbreak of Highly Pathogenic Avian Influenza (HPAI) in Texas.

Since the outbreak of HPAI in the United States, exports of cooked poultry products and products containing eggs as ingredients must comply with heat treatment requirements established by the Korean government. Heat treatment requirements are as follows:

- (1) Heat treatment for cooked poultry products: 70° C (158° F) for a minimum of 30 minutes; or, 75° C (167° F) for a minimum of 5 minutes; or, 80° C (176° F) for a minimum of 1 minute or equivalent treatment.
- (2) Heat treatment for products containing eggs, including dairy products such as ice cream: 55° C (131° F) for a minimum of 15 minute, 60° C (140° F) for a minimum of 5 minutes; or 64° C (147° F) for a minimum of 4.5 minutes; or equivalent treatment.
- (3) A heat treatment statement shall be provided on a form of the certificate issued by the U.S. government agency, including FSIS, APHIS, etc.

USDA is discussing with the MAF a lifting of the import ban placed on fresh and frozen poultry products after the minimum 6-month probation period.

Current information on which U.S. livestock and poultry products are eligible for export to the Korean market can be found on the website of the USDA, FSIS at (http://www.fsis.usda.gov/OFO/export/KOREASO.htm). This website also provides guidance in what documents need to accompany livestock product shipments destined for Korea.

B. StarLink Free Certification

In December 2000, after KFDA detected StarLink protein in U.S. corn shipments, imported food-grade corn and corn-based food products were required to arrive with a StarLink-free certification issued by the exporting country. For U.S. corn shipments, such certification should be issued by the USDA, Grain Inspection, Packers, and Stockyards Administration (GIPSA), or an accredited lab, to minimize potential problems during inspection clearance. Regardless, the sales contract should specify the terms for pre-shipment tests. For processed food products containing corn as an ingredient, certification can be met with a letter, statement, or certificate issued by the manufacturer or the exporter stating the raw corn ingredient was "StarLink-free." All US origin food grade corn and corn-based products must provide a StarLink-free certification at port of entry.

SECTION VII. OTHER SPECIFIC STANDARDS (GMO SAFETY ASSESSMENT & ADVERTISEMENT)

Genetically Modified Organisms (GMO) caught the public's attention and in particular, that of Korean consumer groups during the second half of 1998. On August 20, 1999, KFDA issued the guideline on the safety assessment of genetically modified food products and food additives. This quideline, which established safety assessment requirements and procedures for recombinant foods and food additives, in accordance with Article 4, Paragraph 2 of the Food Sanitation Act, was revised September 1, 2003. The revision mandates safety assessments, thus, foods and food additives developed through recombinant DNA techniques may be distributed commercially after the Commissioner of KFDA confirms that such foods and food additives pose no health risk to humans. Beginning February 27, 2003, KFDA requires mandatory safety assessments for soybeans, corn, and potatoes. Other biotechenhanced crops will be subjected to safety assessments starting February 27, 2005. In accordance with the KFDA guideline and the Food Sanitation Act, any product containing biotech crop ingredients that does not complete the safety assessment by the abovedesignated date will not be permitted for sale in Korea. To date, 25 U.S. crops - roundup ready soybeans, 15 corn events, four cotton events, one canola event, and four potato events – have passed KFDA's safety assessment conducted according to this guideline.

On May 4, 2001, MAF released the draft guidelines for environmental risk assessment (ERA) of biotech crops used for food, feed and seed. MAF finalized guidelines on January 9, 2002, to operate environmental risk assessments of biotech crops on a voluntary basis. To date, 11 applications for environmental risk assessment have been submitted, and two events (one soybean and one corn) out of the 11 have been completed. The ERA will be mandated when the MOCIE's LMO Act goes into effect, which is expected in the later part of 2004. U.S. biotech developers are strongly encouraged to submit application for ERA to the Rural Development Administration (RDA) of MAF as soon as possible to avoid any trade disruption when the ERA becomes mandated. All LMOs, including LMO FFP (food, feed, and processing) and seed, are subject to an ERA.

MAF is also working to prepare a guideline for safety assessments of feed enhanced though biotechnology. No specific plan has been announced but MAF is expected to revise its Feed Management Act to include safety assessments of feed.

On March 5, 2002, the Korean Fair Trade Commission (FTC) announced new advertisement requirements for food containing a biotech-enhanced ingredient effective July 1, 2002. The FTC defines the "presence" of a biotech component as principal information to be provided in an advertisement for any food product required to be labeled by MAF or KFDA in the revision to "Notification of Principle Information on Labeling & Advertisement". According to FTC's advertisement notification, anyone who manufactures or sells biotech-enhanced food, and advertises such products in one of the identified forms below, needs to indicate the presence of the biotech component:

- (1) Newspaper or magazine;
- (2) T.V. commercial (when its running time is greater than two minutes); and,
- (3) Cable T.V. commercial.

Indication shall be made as follows:

(1) "Contains biotech-enhanced food" when presence of a biotech-enhanced component is certain;

(2) "May contain biotech-enhanced food" when presence of a biotech-enhanced component is uncertain.

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

The Korea Industrial Property Office is responsible for registration of trademarks and for review of petitions related to trademark registration. In accordance with the Trademark Law, the trademark registration system in Korea is based on "first-to-file." A person who registers a trademark first has a preferential right to that trademark and Korean law protects the person who has the right over the trademark. To prevent trademark disputes, U.S. companies considering conducting business in Korea are encouraged to first register their trademarks.

SECTION IX. IMPORT PROCEDURES

The Korea Customs Service (KCS), KFDA, National Quarantine Office (for ports that do not have KFDA regional offices), National Veterinary Research & Quarantine Service, and National Plant Quarantine Service are the agencies involved in the import clearance process. Imports of agricultural products generally must receive clearance from several organizations and are, thus, more likely to encounter port delays than other imported products. Delays can be costly due to the perishable nature of many agricultural products. In addition, other organizations may be involved in regulating imports through the administration of licenses or, in some cases, quotas for agricultural products. KCS is responsible for ensuring that all necessary documentation is in place before the product is released from the bonded area. KCS operate the EDI system (Electronic Data Interchange System), and KFDA operates the imported food network system through their regional and national quarantine offices. The KFDA network system is connected to the EDI system, which permits KFDA inspection results to be transmitted more quickly, thus shortening the KCS clearance time. The respective quarantine inspection authorities must clear products subject to plant or animal quarantine inspection before KCS will clear them.

Korea Food & Drug Administration (KFDA) Import Procedures

- (1) The importer or the importer's representative submits the "Import Declaration for Food, etc."
- (2) The type of inspection to be conducted is determined in accordance with the guidelines for inspection of imported food products. The types of inspection that a given food product may be subject include: Document Inspection, Organoleptical Inspection, Laboratory Inspection, and Random Sampling Examination.
- (3) If a product is subject to organoleptical inspection, laboratory inspection and random sampling examination, the KFDA inspector will conduct a field examination and take samples for the laboratory test.
- (4) KFDA conducts the conformity assessment from the information collected, using such items as test results, document inspection results, etc.
- (5) If a product complies with the Korean standards, KFDA issues a certificate for import. An importer can clear products with the KFDA import certificate.
- (6) If a product does not comply with the Korean standards, KFDA will notify the applicant and the regional customs office about the nature of the violation. The importer decides whether to destroy the product, return the shipment to the exporting country, or use it for non-edible purposes. If the violation can be corrected, as with labels, the importer can reapply for inspection after making the corrections.
- (7) For perishable agricultural products, such as fresh vegetable, fruits, etc., an importer can clear the products prior to completion of the laboratory test with a pre-certification authorization from KFDA. In this instance, however, the importer needs to be able to track down the distribution of the given product so the products can be recalled should the laboratory test indicates a violation.

On May 15, 2000, KFDA issued a revision to the Guideline for Inspection of Imported Food Products to add a clause limiting the minimum amount of the initial commercial shipment that it would inspect directly. When the quantity of the imported food is less than 100 kg, the imported food will be inspected by a KFDA-recognized inspection organization – other

than regional KFDA office or National Quarantine Services. Importers shall be responsible for charges associated with import inspection. Detailed information is available from the KFDA's English website: http://www.kfda.go.kr.

On August 18, 2003, MHW issued a revision of the Ministerial Ordinance of the Food Sanitation Act that tightened the import inspection program by requiring a laboratory test of agricultural products every year and for processed products every three years. The U.S. Government expressed concern to the Korean Government about the revision as it would place additional burden on U.S. exporters without justification. In response, the Korean Government reduced the number of chemicals to be tested for and lowered the testing fee on May 21, 2004.

If products are subject to animal quarantine inspection or plant quarantine inspection, in addition to food inspection by KFDA, the animal quarantine certificate or plant quarantine certificate issued by the National Veterinary Research & Quarantine Service (NVRQS) or the National Plant Quarantine Service (NPQS) is required for product clearance, in addition to the KFDA certificate. Inspection by NPQS or NVRQS can take place simultaneously with the KFDA inspection.

Appendix I - Primary Korean Food Agency

- a. Ministry of Health & Welfare: http://www.mohw.go.kr
- b. Ministry of Agriculture & Forestry: http://www.maf.go.kr
- c. Ministry of Maritime Affairs & Fisheries: http://www.mmaf.go.kr
- d . Ministry of Environment: http://www.moen.go.kr
- e. Ministry of Commerce, Industry and Energy: http://www.mocie.go.kr
- f. Korea Food & Drug Administration: http://www.kfda.go.kr
- g. National Veterinary Research & Quarantine Service: http://www.nvrgs.go.kr
- h. National Plant Quarantine Service: http://www.npgs.go.kr
- i. Rural Development Administration: http://www.rda.go.kr
- j. National Agricultural Product Quality Management Service: http://www.naqs.go.kr
- k. National Agricultural Cooperative Federation: http://www.nacf.co.kr
- I. Agriculture & Fishery Marketing Corporation: http://www.afmc.co.kr
- m. Korea Forestry Administration: http://www.foa.go.kr
- n. Korea Rural Economic Institute: http://www.krei.re.kr
- o. Korea Industrial Property Office: http://www.kipo.go.kr
- p. Korea Health Industry Development Institute: http://www.khidi.or.kr
- q. Korea Bio-safety Clearing House: http://www.biosafety.or.kr

Appendix II - WTO Enquiry Point

Names of the SPS Enquiry Point are as follows;

Animal or plant health or zoonosis (including aquatic animals)

Bilateral Cooperation Division International Agriculture Bureau Ministry of Agriculture & Forestry # 1 Choongang-dong, Kwacheon City Kyunggi-do, Korea 427-760

Phone: 82-2-500-1726 or 1727; Fax: 82-2-504-6659

Food Safety

Trade Affairs Division
Ministry of Health & Welfare
1 Choongang-dong, Kwacheon City

Kyunggi-do, Korea 427-760

Phone: 82-2-2110-6457~6452; Fax: 82-2-504-3981

E-mail: jeonghong@mohw.go.kr

International Trade & Legal Affairs Division

Korea Food & Drug Administration # 5 Nokbeon-dong, Eunpyung-ku

Seoul, Korea 122-704

Phone: 82-2-380-1661 or 1662; Fax: 82-2-356-2893

E-mail: wtokfda@kfda.go.kr

Aquatic Animal Health and Sanitation

Trade Promotion Division International Cooperation Bureau Ministry of Maritime Affairs & Fisheries # 139 Choongjungro 3-ga, Seodaemun-ku

Seoul, Korea 120-715

Phone: 82-2-3148-6840/3; Fax: 82-2-3148-6844

Appendix III - List of Available Regulations or English Translated Regulations

The following regulations are available either in English or Korean from the Agricultural Affairs Office in Seoul. Contact information is:

Agricultural Affairs Office U.S. Embassy

Seoul, Korea

Local address:
32 Sejongro, Jongro-ku
Seoul, Korea
U.S. address:
US Embassy, Seoul
Unit 15550 – AGR
Tel: 82-2-397-4297
APO, AP 96205-5550

Fax: 82-2-738-7147 E-mail: AgSeoul@usda.gov

- 1. Food Sanitation Act
- 2. Presidential Decree to the Food Sanitation Act
- 3. Ministerial Ordinance to the Food Sanitation Act
- 4. Labeling Standards for Food et al.
- 5. Korean Food Code
- 6. Korean Food Additive Code
- 7. Livestock Processing Control Act
- 8. Presidential Decree to the Livestock Processing Control Act
- 9. Ministerial Ordinance to the Livestock Processing Control Act
- 10. Livestock Code
- 11. Labeling Standards for Livestock Products
- 12. Agricultural Products Quality Control Act
- 13. Country of Origin Regulations
- 14. Sustainable Agriculture Promotion Act
- 15. Presidential Decree to the Sustainable Agriculture Promotion Act
- 16. Ministerial Ordinance to the Sustainable Agriculture Promotion Act

- 17. Guidelines for Safety Assessment of Food & Food Additives Developed Through Recombinant DNA techniques
- 18. Guidelines for Risk Assessment of Biotech Crops for Environmental Release
- 19. Guidelines for Labeling Standards for Non-Processed GMO Products
- 20. Guidelines for Labeling Standards for Processed Food Products Containing GM Ingredients
- 21. LMO Act

Appendix IV - Standards for Packaging, Container or Equipment for Food Products

Standards for packaging, container, or equipment for food products are set in the Korean Food Code. This regulation is available in both English and Korean language as part of the Korean Food Code mentioned above.

Appendix V - U.S. Laboratories Authorized to Inspect on Behalf of the Korean Government (KFDA)

KFDA operates a program that recognizes foreign laboratories as official testing laboratories. This program aims to enhance the efficiency of conducting inspection of imported food. KFDA authorizes foreign laboratories and recognizes inspection certificates or certificates of laboratory test results issued by these authorized laboratories. As of now, there are two U.S. laboratories that have been authorized by KFDA. They are:

1. Oregon Department of Agriculture's Export Service Center

The Oregon Department of Agriculture's Export Service Center (ESC) is a one-stop technical assistance center for U.S. food manufacturers and exporters. It is designed to reduce obstacles for exporting products. The ESC has been certified by the Korean Food & Drug Administration to do food related testing, such as residue and microbiological testing on food and beverages and food package testing, for products bound for Korea. A certificate of inspection from this lab usually expedites clearance inspections at Korean Customs. The ESC offers a range of technical services, including product evaluation and certification. They will evaluate products for foreign country requirements and issue a certificate that minimizes the chances of product rejection. For more information on the services which the Export Service Center provides contact:

Oregon Department of Agriculture Export Service Center

1200 N.W. Naito Parkway, Suite 204 Portland, Oregon 97209-2835

Tel: 503-872-6644; Fax: 503-872-6615

E-mail: esc-food@oda.state.or.us

2. Omic USA Inc.

Omic USA is the second U.S. laboratory to be recognized by the Korea Food & Drug Administration as an official foreign testing laboratory. The contact information follows:

Omic USA Inc.

Mr. Ryuichi Kurosawa, President 1200 N.W. Naito Parkway Portland, Oregon 97209

Tel: 503-224-5929; Fax: 503-223-9436